

510(k) Summary of Safety and Effectiveness

Submitter

Mediana Co., Ltd.

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Date Summary Prepared: May 5th, 2011

Device Name

Trade Name: YM6000, patient monitor

Common Name: Patient Monitor

Classification Name: Monitor, Physiological, Patient (with arrhythmia detection or alarms)
(21CFR870.1205) also contains

Monitor, Cardiac (including cardiometer and rate alarm)
(21CFR870.2300)

System, measurement, blood-pressure, non-invasive
(21CFR870.1130),

Electrocardiograph (21CFR870.2340)

Oximeter (21CFR870.2700)

Analyzer, gas, carbon-dioxide, gaseous-phase (21CFR868.1400)

Computer, Blood-Pressure (21CFR870.1110)

Transmitters and receivers, physiological signal, radiofrequency
(21CFR870.2910)

Classification: Class II

Product code: MHX

Predicate Devices (Legally Marketed Devices)

The predicate devices for Patient monitors, Model YM6000 are:

- **Omron Healthcare Inc.** Omron Model HBP-2070 Vital Signs Monitor
cleared by FDA through 510(k) No. K082812,
- **Spacelabs Medical Inc.** mCare 300 Vital Signs Monitors, Model 91220
cleared by FDA through 510(k) No. K062095,
- **Omron Healthcare Inc.** Colin Press Mate Model BP-S510
cleared by FDA through 510(k) No. K063690,
- **Mediana Co., Ltd.** Lucon M-Series Patient Monitor, Model M20 and M30
cleared by FDA through 510(k) No. K100217

Device Description

The YM6000 patient monitor is to monitor electrocardiography (ECG), Arrhythmia, ST segment, heart rate (HR), pulse rate, noninvasive blood pressure (systolic, diastolic and mean arterial pressures), functional arterial oxygen saturation, invasive blood pressure, respiration, capnography (EtCO₂ and InCO₂) and temperature for adult, pediatric and neonate in patients in general hospital and alternate care facilities by medically trained personnel. This monitor is available for sale only upon the order of a physician or licensed health care professional.

The YM6000 patient monitor is a lightweight and compact device (341 × 305 × 172 (mm) (W × H × D) and 5.5 kg) powered by AC mains (100-240VAC, 50-60Hz) and also powered by internal battery. The monitor provides patient data and monitoring status on TFT-LCD displays.

Intended Use

The YM6000 monitor is intended to be used to monitor electrocardiography, heart rate, pulse rate, noninvasive blood pressure (systolic, diastolic and mean arterial pressures), functional arterial oxygen saturation, invasive blood pressure, respiration, capnography (EtCO₂ and InCO₂) and temperature for adult, pediatric and neonate patients in all areas of a hospital and hospital-type facilities. Monitor users should be skilled at the level of a technician, doctor, nurse or medical specialist.

Note: Hospital use typically includes such areas as general care floors, operating rooms, special procedure areas, intensive and critical care area, within the hospital. Hospital-type facilities include physician office-based facilities, sleep labs, skilled nursing facilities, surgicenters, and sub-acute centers.

Note: The medically skilled and trained user can be any clinicians like doctor and nurse who know how to take and interpret a patient's vital signs. These clinicians must take the direct responsibility for patient life. It can include a care-giver or medically trained interpreter who is authorized under the appropriate clinical facility procedure to support the patient care. Any inappropriate setting, especially the limit alarm or alarm notification setting can lead the hazardous situation that injures the patient or harms the patient or threatens the patient life. The special attention to assign the trained user who can adjust the patient setting of the patient monitor should be essentially paid.

Summary of Technical Characteristics of the Device Compared to the Predicate Devices (Legally Marketed Devices)

The Mediana Patient Monitor, Model YM6000 is substantially equivalent to the Colin Press Mate Model BP-S510, Lucon M-series Patient Monitor, Model M20 and M30, Omron Model HBP-2070 Vital Signs Monitor, and mCare 300 Vital Signs Monitor, Model 91220.

- The Model YM6000 uses the Mediana ECG module, MDE-1 manufactured by Mediana Co., Ltd. which is identical to the module used in the Model M20, M30 and Model HBP-2070. So the Electrocardiogram (ECG) and heart rate specifications for the Model YM6000, Model M20, M30 and Model HBP-2070 are identical,
- The Model YM6000 uses the Omron NIBP module M3200 which is identical to the module used in the Model BP-S510, Model M20, M30 and Model HBP-2070. The non-invasive blood pressure (NIBP) and pulse rate specifications for the Model YM6000, Model BP-S510, Model M20, M30 and Model HBP-2070 are identical. The circuitry, algorithm and cuffs in

both models are the same manufactured by Omron Healthcare Inc. Also, all devices comply with the AAMI performance standard SP-10 & IEC60601-2-30 and have same measurement technology,

- The Model YM6000 uses the Nellcor SpO₂ module, NELL-3, which is identical to the module used in the Model BP-S510, Model M20, M30 and Model HBP-2070. The SpO₂ specifications for the Model YM6000, Model BP-S510, Model M20, M30 and Model HBP-2070 are identical. The circuitry, algorithm and sensors are the same as SpO₂ module used in above monitors, is manufactured by Nellcor Inc. Also, all devices comply with the performance standard ISO9919,
- The respiration can be obtained from either the Electrocardiogram (ECG) channel or the Capnography (EtCO₂) channel. The algorithm of Impedance measurement in the Model M20, M30 and Model HBP-2070 is identical to that in Model YM6000 and the respiration specification for the Model YM6000, Lucon M-series (Model M20, M30) and Model HBP-2070 are identical because the respiration measurement (Thoracic Impedance) for Model YM6000, Lucon M-series (Model M20, M30) and Model HBP-2070 is from ECG module that are the same module designed and manufactured by Mediana Co., Ltd.,
- And also Lucon M-series (Model M20, M30) and Model 91220 have identical performance of respiration measurement (Airway Measurement) with Model YM6000. Because respiration measurement (Airway Measurement) is from Capnography module and these devices use the same Capnography module which manufactured by Philips Respironics Inc.,
- The Model YM6000 uses the thermometry MDT-1 module which is identical to used in the Lucon M-series (Model M20, M30) and Model HBP-2070. The temperature measurement method for the Model YM6000, Lucon M-series (Model M20, M30) and Model HBP-2070 are equivalent. Also all of device uses the YSI probes/probe covers,
- The pulse rate derived from the non-invasive blood pressure (NIBP) channel is from M3200 NIBP module in the Model YM6000. This M3200 module is identical to that in the Model BP-S510, Lucon M-series (Model M20, M30) and Model HBP-2070. And the pulse rate derived from the Pulse Oximetry (SpO₂) channel is from NELL-3 SpO₂ module in the Model YM6000. This NELL-3 module is identical to that in the Model BP-S510, Lucon M-series (Model M20, M30) and Model HBP-2070,
- The Model YM6000 uses the Respironics Capnography module, Capnostat 5 and LoFlo C5 which have already been registered in FDA by Philips Respironics Inc. (#K042601 is for Capnostat 5, #K053174 is for LoFlo C5). Both modules are identical to the modules used in the Lucon M-series (Model M20, M30) and Model 91220. All devices have identical technology and operation of theory in Capnography module,
- The Model YM6000 uses the same measurement technology with the Model BP-S510 for Invasive Blood Pressure. The IBP technology is most traditional and typical method among measuring the patient parameter. The Invasive blood pressure measurement performance of the Model YM6000 is similar to the Model BP-S510 by using same measurement technology. And both devices comply with the IBP performance standard, IEC60601-2-34.
- The YM6000 monitor as well as the predicate devices has internal power source, a rechargeable lead acid battery and AC power.

Summary of Performance Testing

The Mediana patient monitor, Model YM6000 substantially have been tested in accordance with the system V & V plan (#P AA00-00005) and summary included with the submission using production equivalent units prior to release to market.

A risk analysis identifying potential hazards and documenting mitigation of the hazards has been developed and applied as part of Mediana design control procedure. Mediana's quality system confirms to 21 CFR820, ISO13485 and CMDCAS ISO13485 certified by DNV (Det Norske Veritas).

Conclusions

As stated above, the Mediana patient monitors, Model YM6000 is safe and effective and comply with the appropriate medical device standards and are substantially equivalent to the earlier identified predicate devices.

- End of Section -



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

NOV - 9 2011

Mediana Co., Ltd.
c/o Ms. Charlie Mack
President
International Regulatory Consultants
7325 Joyce Way
Echo, OR 97826

Re: K112190
Trade/Device Name: YM6000, Patient Monitor
Regulatory Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: II (two)
Product Code: 74 MHX
Dated: October 16, 2011
Received: October 24, 2011

Dear Ms. Mack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

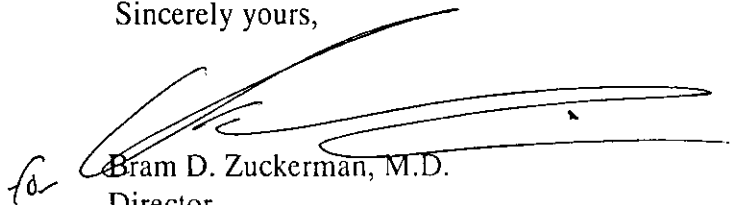
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a horizontal line. To the left of the signature, the letters "fo" are handwritten.

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant:

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 Gangwon-do, Korea
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510(k) Number: _____

Device Name: YM6000, Patient Monitor

Indications for Use:

The YM6000 monitor is intended to be used to monitor electrocardiography, heart rate, pulse rate, noninvasive blood pressure (systolic, diastolic and mean arterial pressures), functional arterial oxygen saturation, invasive blood pressure, respiration, capnography (EtCO₂ and InCO₂) and temperature for adult, pediatric and neonate patients in all areas of a hospital and hospital-type facilities. Monitor users should be skilled at the level of a technician, doctor, nurse or medical specialist.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter
 (Per 21CFR801.109)


 (Division Sign-Off)
 Division of Cardiovascular Devices

510(k) Number K112190